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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,903	08/22/2003	Daniel M. Lieberman	3998P2652	1335
23504 7590 03/28/2007 WEISS & MOY PC 4204 NORTH BROWN AVENUE SCOTTSDALE, AZ 85251			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/28/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/646,903

Applicant(s)

LIEBERMAN, DANIEL M.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 14-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This action is in response to applicant's arguments submitted 20 February 2007.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims are rejected under 35 U.S.C. 102(e) as being anticipated by WILD (US 6,605,036).

Regarding claims 11,14-16, Wild teaches a method and apparatus for treating a subdural hematoma (Col 1 line 53) comprising a dual lumen catheter (1) with a passive drainage channel (10) with perforations (at distal end) and multiple irrigation channels (9) with perforations (at distal end).

Regarding claim 17, the drainage perforations have a diameter of less than 2mm (Col 12 line 28)

Regarding claim 18 and 19, a pressure valve is coupled to the irrigation channel ("A pressure and volume monitoring system of conventional construction is preferred for this purpose", Col 7 line 60)

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Regarding claims 20 and 21, "The passive fluid escape channel is connected proximally to a drainage tube providing gravity drainage and collection of all fluids."

(Col 7 line 46)

Regarding claim 22, a hole is drilled in the skull to access the subdural space (inherent to accessing the subdural space)

Regarding claim 23, a tuohy needle is provided (outer tube 25)

Regarding claim 24, a guidewire is provided (steerable push-pull wires)

Regarding claim 25, a stylette is provided (rigid telescope 2 functions in the same manner as a stylette, to provide temporary rigidity to the catheter)

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wild as applied to claim 14 above, and further in view of DARDIK et al (Journal of Vascular Surgery).

Wild teaches the limitations of the dual lumen catheter as above, but is silent on the duration of irrigation and drainage of the subdural hematoma.

Dardik et al teach that drains are removed from patients after three days (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dual lumen catheter for three days, as taught by Dardik et al, as a well known medical procedure.

### ***Response to Arguments***

5. Applicant's arguments filed 20 February 2007 have been fully considered but they are not persuasive.

Regarding claim 11, applicant has argued that irrigation channel tubes must support the irrigation channel inside the drainage channel. Wild's irrigation channel is taken as the group of tubes 9 and 9 (Fig 17) which are supported inside drainage channel 10 by the walls of the individual tubes 9. Regarding the argument that irrigation channel is only at the end of the distal portion, this limitation is not found in the claims.

Regarding claim 14, applicant has argued that Wild does not irrigate the subdural space. Wild teaches providing an irrigation fluid to the subdural space (via lumens 9). There is also passive drainage lumen 10 which collects any fluid in the subdural space. Applicant seems to believe that the endoscope of Wild is not capable of use in the subdural space. However, Wild sets out in the discussion of the prior art the types of procedures his device is attempting to improve upon, including the treatment of subdural hematomas. Wild goes on to discuss the very limitations the applicant has pointed out in his declaration and discusses how his new endoscope overcomes these limitations (i.e. by being more flexible). The device of Wild is specifically designed for use in neurological surgery. Applicant further proposes that a catheter with multiple

"channels" is not a "dual lumen" catheter. In the art, the terms "channel" and "lumen" are interchangeable and Wild clearly shows a catheter with at least to "lumens" in Fig 17.

Regarding claim 16, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the distance the catheter is inserted into the subdural space) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding claim 23, a tuohy needle is defined as a needle with a lateral opening the distal end. Element 25, shown in Fig 2, has this same structure and causes the catheter to bend at 45 degrees in the same manner as a tuohy needle.

Regarding claim 24, the steerable wires act as guidewires by directionally positioning the catheter in the subdural space.

Regarding claim 25, the rigid telescope has the same structure as a stylette and is used to give the catheter rigidity, as claimed.

Regarding claims 26 and 27, the issue at question is whether or not one of ordinary skill in the art would leave a subdural drain in place for approximately 1-2 or over 3 days. Dardik teaches a method of treating patients who exhibited subdural hematomas and where drains were removed after 3 days. Therefore it is well known to remove a hematoma drain after 3 days.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

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